

Executive Summary

The Office of Public Health and Science (OPHS) in the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS) conducted a farm-to-table risk assessment to evaluate the public health impact from *Escherichia coli* O157:H7 in ground beef. This risk assessment was initiated in response to the identification of *E. coli* O157:H7 in cattle, on carcasses, and in ground beef, as well as heightened public awareness of the association of *E. coli* O157:H7 with foodborne outbreaks that have resulted in severe illness and death. The purpose of this risk assessment is to systematically evaluate and integrate available scientific data and information to

- provide a comprehensive evaluation of the risk of illness from *E. coli* O157:H7 in ground beef based on currently available data,
- estimate the likelihood of human morbidity and mortality associated with specific numbers of *E. coli* O157:H7 in ground beef servings,
- estimate the occurrence and extent of *E. coli* O157:H7 contamination at points along the farm-to-table continuum,
- provide a tool for analyzing how to most effectively mitigate the risk of illness from *E. coli* O157:H7 in ground beef (one that is useful for Pathogen Reduction and Hazard Analysis and Critical Control Point applications),
- identify future food safety research needs, and
- assist FSIS in the review and refinement of its integrated risk reduction strategy for *E. coli* O157:H7 in ground beef.

BACKGROUND

E. coli O157:H7 was first recognized as a foodborne pathogen with major public health consequences in 1982, when it was associated with two outbreaks of bloody diarrhea in Oregon and Michigan. An estimated 62,000 cases of symptomatic *E. coli* O157:H7 infections occur annually in the United States due to foodborne exposures, resulting in approximately 1,800 hospitalizations and 52 deaths. As many as 3,000 cases may develop hemolytic uremic syndrome annually. Surveillance data indicate that the highest incidence of illness from *E. coli* O157:H7 occurs in children under 5 years of age.

Epidemiological evidence indicates that ground beef is a primary source of human exposure to *E. coli* O157:H7. Between 1982 and 1993, ground beef was identified as the transmission source in 54% of *E. coli* O157:H7 outbreaks. Of the *E. coli* O157:H7 outbreaks reported between 1993 and 1998, most (72%) were foodborne. Of the foods implicated in these outbreaks, ground beef was the most common (45%) source. Studies of sporadic cases of *E. coli* O157:H7 illness also identified ground beef as the primary source of human exposure.

As the public health regulatory agency responsible for ensuring that meat and poultry products are properly labeled, wholesome, and safe, FSIS took additional steps to prevent the occurrence of *E. coli* O157:H7 in ground beef sold to the U.S. public, including improving its sampling and detection methods for *E. coli* O157:H7 in ground beef, strengthening consumer education initiatives that are focused on proper cooking and handling of ground beef, and setting policy declaring *E. coli* O157:H7 in raw ground beef an adulterant. On August 18, 1998, FSIS announced plans to develop the farm-to-table risk assessment documented in this report.

STRUCTURE AND SCOPE OF THE *E. COLI* O157:H7 RISK ASSESSMENT

The *E. coli* O157:H7 risk assessment is a *baseline* risk assessment in that it reflects, to the extent practicable, a full range of current practices, behaviors, and conditions in the farm-to-table continuum (production, slaughter, processing, transportation, storage, preparation, and consumption) (Figure ES-1). Scientific data and information available through July 2001 were integrated into the generally accepted framework for microbiological risk assessments: hazard identification (Chapter 2), exposure assessment (Chapter 3), hazard characterization (Chapter 4), and risk characterization (Chapter 5). Each component of the assessment has a distinct role.

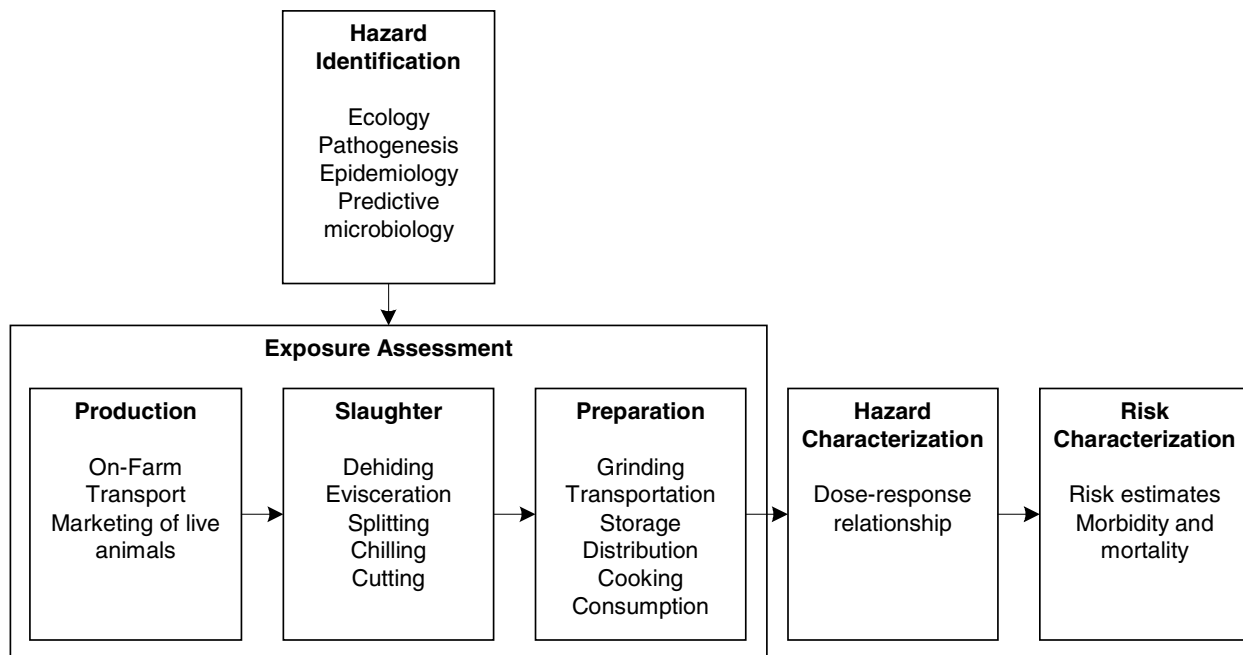


FIGURE ES-1 Farm-to-table risk assessment model for *E. coli* O157:H7 in ground beef.

Hazard identification characterizes *E. coli* O157:H7 using data from ecology, pathology, epidemiology, and microbiology.

Exposure assessment comprises three modules—production, slaughter, and preparation—and uses probabilistic techniques to model the prevalence and concentration of *E. coli* O157:H7 in live cattle, carcasses, beef trim, and, ultimately, a single serving of cooked ground beef. Data for the exposure assessment include herd and within-herd prevalence of *E. coli* O157:H7, slaughter processing conditions including decontamination steps, consumer and retail storage and cooking behaviors contributing to the growth or decline in the number of *E. coli* O157:H7 organisms in ground beef servings, and consumer demographics (e.g., age of the consumer and location of the meal) and consumption patterns. Seasonal differences in herd prevalence of *E. coli* O157:H7 infection were also included.

Hazard characterization quantifies the nature and severity of the adverse health effects (i.e., illness or death) (response) associated with exposure to a given number of *E. coli* O157:H7 organisms in a ground beef serving (dose). For *E. coli* O157:H7, the precise relationship between the number of organisms consumed and the resulting adverse human health event is not known. The *E. coli* O157:H7 dose-response function was derived using information from three sources: (1) the estimated annual number of symptomatic *E. coli* O157:H7 infections due to ground beef exposure, (2) the estimated number of contaminated ground beef servings from the exposure assessment, and (3) the lower and upper bound dose-response curves derived using surrogate pathogens. The upper and lower bound dose-response curves describe the uncertainty about the probability of symptomatic illness at an ingested dose (the median *E. coli* O157:H7 dose-response function). Seasonal variability in reported *E. coli* O157:H7 cases was also included.

Risk characterization integrates the results of the exposure assessment and hazard characterization to estimate the risk of illness from *E. coli* O157:H7 in ground beef. Risk estimates are provided for individuals, a community in a simulated outbreak scenario, and the U.S. population. The variability of risk among the U.S. population is considered according to differences in seasonal exposure and host susceptibility (based on the age of the consumer). Also included in the risk characterization is a sensitivity analysis to identify factors that most influence the occurrence and number of *E. coli* O157:H7 organisms in ground beef and the subsequent risk of illness. Factors that most influence the risk of illness, but for which there were limited data and information, are identified as important food safety research areas.

As announced in the *Federal Register* (Volume 63, page 44232), this risk assessment is confined to *E. coli* O157:H7 exposure from the consumption of ground beef servings (e.g., hamburgers, meat balls, and meat loaf) in the United States. Only *E. coli* O157:H7 generated from infected cattle and subsequent contaminated beef trim and ground beef were considered. Exposures from cross-contamination or other sources of *E. coli* O157:H7 (e.g., nonground beef foods, water, and fomites) were outside the scope of this assessment. This risk assessment also does not explicitly model imported beef as distinct from domestic beef. However, seasonal variation in the incidence of *E. coli* O157:H7 infection in U.S. cattle and human population is included.

RESULTS OF THE *E. COLI* O157:H7 RISK ASSESSMENT

The risk assessment yields intermediate and final outputs in the form of distributions that characterize the variability and uncertainty in estimates of a variety of risk assessment endpoints or human illnesses. The exposure assessment indicates that feedlot cattle (steers and heifers) have a higher prevalence of *E. coli* O157:H7 infection than culled breeding cattle (cows and bulls) and that prevalence is higher during June to September than October to May. Although only a fraction of infected live cattle result in contaminated carcasses, thousands of pounds of meat trim from these carcasses are combined in the grinding process. Consequently, although the

number of *E. coli* O157:H7 organisms in these grinder loads may be quite low, the proportion of grinder loads that contain at least 1 *E. coli* O157:H7 organism is expected to be high. Most ground beef servings are cooked in the United States. Less than 0.007% to 0.018% (depending on seasonal exposure) of cooked ground beef servings contain *E. coli* O157:H7 organisms. However, considerable uncertainty exists regarding the frequency of cooked ground beef servings that have 1 or more *E. coli* O157:H7 present.

The median probability of illness for the general U.S. population due to *E. coli* O157:H7 from a serving of ground beef is estimated to be 9.6×10^{-07} or about 1 illness in every 1 million servings. Based on a U.S. population risk of illness from *E. coli* O157:H7-contaminated ground beef, the per serving probability of being hospitalized but recovering is 2.0×10^{-8} , of developing HUS is 4.2×10^{-9} , and of death is 5.9×10^{-10} . When variation in seasonal exposure is considered, the risk of illness from *E. coli* O157:H7 is about 1 in every 600,000 ground beef servings consumed during June through September and about 1 in every 1.6 million ground beef servings consumed during October through May. Children aged 0 to 5 may have an almost 2.5 times higher risk of illness (2.4×10^{-6}) from *E. coli* O157:H7 in ground beef than does the general U.S. population.

Factors that most influence the occurrence and extent of *E. coli* O157:H7 contamination in ground beef and subsequent risk of illness were identified using sensitivity analyses. The occurrence and extent of *E. coli* O157:H7 contamination in beef trim and subsequent grinder loads was most influenced by feedlot and within-feedlot prevalence, occurrence and extent of carcass contamination, effectiveness of decontamination procedures, and the effect of carcass chilling. The occurrence and extent of *E. coli* O157:H7 contamination in cooked ground beef servings was most influenced by the proportion of ground beef that was frozen, the maximum *E. coli* O157:H7 population density in ground beef servings, and storage and cooking conditions. The importance of these factors varied by season (June to September or October to May). Although some factors influenced the occurrence of *E. coli* O157:H7 in combo bins, grinder loads, or ground beef servings, others were more important in influencing the extent of *E. coli* O157:H7 contamination in these units.

RESEARCH NEEDS

The *E. coli* O157:H7 risk assessment is structured to allow incorporation of additional data as they become available. The determination of which data would be most beneficial is based on areas identified as important and for which there is limited information. Several areas of food safety research would strengthen the certainty of estimates from this risk assessment, including

- additional information on *E. coli* O157:H7 contamination of cattle and carcasses following dehiding;
- data on the effect of carcass chilling on increases or decreases in *E. coli* O157:H7 organisms;
- predictive microbiological data on the increase and decrease in the number of *E. coli* O157:H7 organisms in ground beef under various storage and preparation conditions along with estimates of the frequencies of occurrence of these storage and preparation conditions;

- information on the maximum density of *E. coli* O157:H7 organisms in ground beef servings as a result of matrix effects, competitive microflora in ground beef, and environmental conditions (e.g., pH, water activity); and
- Data on retail (hotels, restaurants, and institutions [HRI]) and consumer storage, cooking, and consumption (frequency and serving size) patterns by type of ground beef meal (e.g., grilled hamburger or baked meat loaf) and season.

NEXT STEPS

Some cautions on the appropriate use of this risk assessment should be noted. First, the conclusions are based on current data and scientific assumptions. Additional data will be incorporated into the model as they become available. Second, the results provide only part of the information needed by decision makers and regulators. This risk assessment does not address such issues as cost, feasibility, or effectiveness of possible interventions. These analyses are necessary before deciding which of many possible policies should be implemented regarding *E. coli* O157:H7 in ground beef.

Future plans for this risk assessment include evaluating the effect that various mitigation strategies may have in decreasing the occurrence of *E. coli* O157:H7 in ground beef and associated human illnesses. FSIS also plans to expand the risk assessment to include other beef products (i.e., nonintact beef).

FSIS is releasing this draft report documenting the baseline risk assessment on *E. coli* O157:H7 in ground beef for public comment and scientific peer review by the National Academy of Sciences. Thus, the risk assessment is a “work in progress.” FSIS invites public input to further strengthen this farm-to-table baseline risk assessment for *E. coli* O157:H7 in ground beef.

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